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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/802,240

03/17/2004

Paolo Cavassini

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EXAMINER

SASAN, ARADHANA

ART UNIT

PAPER NUMBER

1615

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/802,240

Applicant(s)

CAVASSINI ET AL.

Examiner

Aradhana Sasan

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1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 6/4/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. Claims 1-59 are being presented for examination.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 06/04/2004 was filed.

The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98.

Accordingly, the examiner is considering the information disclosure statement.

See attached copy of PTO-1449.

Specification

3. The disclosure is objected to because of the following informalities: On Page 18, line 16; microencapsulation is misspelled "microencapsulation". On Page 20, line 19; negligible is misspelled "negigeable".

Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-8, 22-40, 46-56, are rejected under 35 U.S.C. 103(a) as being unpatentable over Iijima et al. (US 4,948,589).

The claimed invention is a composition of matter comprising particles with a core of choline chloride as a dry, crystalline powder and a coating of carnauba wax and a

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hydrophobic substance (selected from vegetable oils). Feed pellets, premix for feed, and mash feed containing the composition are also claimed.

Iijima teaches a granular composition containing choline for a ruminant. The granular composition is "capable of reaching an abomasums and downstream thereof substantially in the form of granules, without easily dissolved or decomposed in the rumen" (Col. 2, lines 3-9). Choline chloride is a preferable choline derivative (Col. 2, lines 45-46). Hydrophobic agents such as hydrogenated palm oil, hydrogenated soybean oil, stearic acid, and carnauba wax are disclosed as binders and overcoating agents for the granules (Col. 3, lines 34-40 and lines 50-56). It is also disclosed that the granular composition may contain "any ingredients conventionally used in the animal feed, especially for a ruminant" (Col. 4, lines 9-15). The choline chloride is powdered since the particle size is disclosed. "Cholines having an average particle size of 100 μ m or less ... and a maximum particle size of 150 μ m or less ... are granulated with excipients and hydrophobic binders" (Col. 4, lines 18-27). The particle size of choline chloride is achieved by grinding in an appropriate grinder (Col. 4, lines 42-46). Granulation methods such as fluidized granulation and agitation granulation are disclosed (Col. 5, lines 44-53). "... When the agitation granulation is used, relatively spherical or round granulated particles, which are suitable for subsequent coating, can be advantageously obtained ... the fluidizable binder is migrated to the surface of the granules during the granulation to form a surface layer. As a result, the cholines and other powder to be protected is relatively located in the inside portion of the granules" (Col. 5, lines 54-64). The resultant granules have a particle size of 0.5 to 2.5mm (Col. 6,

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lines 49-51). The choline granules "are overcoated with a thin film by adding 20 to 40 parts, preferably 20 to 30 parts by weight, of a molten mixture, ... of a hydrophobic overcoating agent and a solubility modifier ..." (Col. 6, line 67 to Col. 7, line 6). "When the dissolution test of Example 1 was carried out with respect to the inner granules of Example 1 in which the overcoating was not applied, the dissolution rate in the rumen solution was 99%. As a result, the choline chloride was substantially completely dissolved in a rumen corresponding solution. Thus, when the coating is not applied, the desired resistance is not obtained" (Col. 9, lines 44-52).

Iijima does not expressly teach the overcoating of the choline chloride comprising an outer layer of carnauba wax and an inner layer of a hydrophobic substance.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a composition of choline chloride in the core, coated with hydrophobic materials such as carnauba wax and hydrogenated oils, as suggested by Iijima, and provide layers (outer and inner) of overcoating with these hydrophobic components, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because in the art of coating granules or core components, the layers of coating are intrinsic. One skilled in the art would modify the components of the layers according to the desired stability of the core. Iijima teaches, "the binder and the overcoating agent may be the same or different, but the use of the same or similar substances is preferable because the good coating can be obtained when the compatibility of the binder with the overcoating agent is good" (Col. 7, lines 47-51). One skilled in the art would know the

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compatibility of hydrophobic components of the overcoating such as carnauba wax and hydrogenated oils. Moreover, one skilled in the art would know that carnauba wax melts at a higher temperature than hydrogenated vegetable oils and would use that as the outer layer or coating in order to further stabilize the coated granule in the rumen.

Regarding instant claim 1, the limitations of dry, crystalline choline chloride, coated with carnauba wax and a hydrophobic substance that is ruminally protected would have been obvious to one skilled in the art over the teaching of Iijima as stated above.

Regarding instant claims 2-4, the limitation of micronized choline chloride would have been obvious to one skilled in the art over the Iijima teaching of ground choline chloride and particle size of 150 μ m. One skilled in the art would grind the choline chloride and vary the particle size in the composition in order to optimize the rumen protection.

Regarding instant claims 5-6, the limitation of choline chloride percentage in the core would have been obvious to one skilled in the art over the Iijima teaching of choline chloride coated core. One skilled in the art would vary the amount of choline chloride in the core during routine experimentation, in order to optimize the efficacy of the coated composition. The recited percentages are obvious variants unless there is evidence of criticality or unexpected results.

Regarding instant claims 7-8, and 39-40, the limitations of the core comprising additional substance, particularly a flow modifier, would have been obvious to one skilled in the art over the teaching of Iijima where talc is used in the core composition

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along with choline chloride (Col. 8, Example 1 Granulation, lines 32-36). Talc is known as a flow modifier in the art.

Regarding instant claims 22-26, the percentages of the additional substances in the core would have been obvious to one skilled in the art over the teaching of Iijima. The percentages are obvious variants unless there is evidence of criticality or unexpected results.

Regarding instant claims 27-28, the percentages of the core weight with respect to the whole particle would have been obvious to one skilled in the art over the teaching of Iijima. One skilled in the art would vary the percentage of core with respect to the coatings during the process of routine optimization.

Regarding instant claims 29-30, the percentages of the carnauba with respect to the outer layer would have been obvious to one skilled in the art over the teaching of Iijima. One skilled in the art would vary the percentage of carnauba wax with respect to the outer layer during the process of routine optimization.

Regarding instant claims 31-38, the limitations a rigidity-controlling agent mixed with carnauba wax would have been obvious to one skilled in the art over the teaching of Iijima. Iijima teaches hydrogenated palm oil, hydrogenated bean oil, hydrogenated coconut oil, stearic acid, carnauba wax etc. as hydrophobic binders (Col. 3, lines 34-40). One skilled in the art would find it obvious to combine the lower melting hydrogenated vegetable oils with the higher melting carnauba wax in order to control the rigidity of the coating layer. One skilled in the art would know that the rigidity of the outer coating layer is primarily provided by the higher melting carnauba wax, and by adding a lower melting

point component (such as a hydrogenated vegetable oil) would modify the rigidity of the outer coating layer. The percentages of the rigidity-controlling agent would be obvious variants unless there is evidence of criticality or unexpected results.

Regarding instant claims 46-49, the limitations of outer coating percentage and inner coating percentage would have been obvious to one skilled in the art because the percentage of the inner and outer coatings would be varied during the process of routine optimization of stabilizing choline chloride in the rumen.

Regarding instant claims 50-54, the limitations of lipids as the hydrophobic substances would have been obvious to one skilled in the art given the teaching of hydrogenated oils and stearic acid by Iijima.

Regarding instant claims 55-56, the percentage of the protective coating with respect to the whole particle would have been obvious to one skilled in the art because the percentage of the protective coating would be varied during the process of routine optimization of stabilizing choline chloride in the rumen.

6. Claims 9-14, 57-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iijima et al. (US 4,948,589) in view of Richardson (US 6,797,291).

The teaching of Iijima is stated above.

Iijima does not expressly teach silicates as flow modifiers.

Richardson teaches compositions for stabilizing a hygroscopic bioactive substance, such as choline chloride and also providing adequate rumen protection in ruminant feeds (Abstract). The choline chloride is encapsulated "with a lipid coating in

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an amount sufficient to retain at least about 60 wt % of the hygroscopic ingredient after the encapsulated ingredient is combined with the moist composition for a time period of at least about 1 day; and ... combining the encapsulated hygroscopic ingredient with the moist composition" (Col. 3, lines 41-47). The hygroscopic ingredient can be choline chloride (Col. 3, line 48). The moist composition is a ruminant feed (Col. 3, lines 54-55). Hydrogenated vegetable (soybean) oil is the preferred lipid for coating (Col. 3, lines 64-65). Hydrogenated vegetable oil can be mixed with lesser amounts of wax (Col. 3, line 66 to Col. 4, line 5). It is further disclosed that, "skilled practitioners also recognize that flow agents, such as finely-divided silica, can be admixed with the particles of the invention to facilitate handling" (Col. 10, lines 11-13).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a composition of choline chloride in the core, coated with hydrophobic materials such as carnauba wax and hydrogenated oils, as suggested by Iijima, and use silica as the flow agent, as taught by Richardson, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Richardson teaches, "skilled practitioners also recognize that flow agents, such as finely-divided silica, can be admixed with the particles of the invention to facilitate handling" (Col. 10, lines 11-13).

Regarding instant claim 10, the limitation of aluminosilicate would have been obvious to one skilled in the art over the sodium aluminosilicate teaching of Richardson. Richardson teaches "the encapsulates can contain additives whose role is to facilitate

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the implementation of the techniques for preparing these encapsulates or to improve the physicochemical characteristics ... if included, these additives generally represent only a few percent by weight of the coating" (Col. 9, lines 46-62).

Regarding instant claim 11, the flow modifiers including silica would have been obvious to one skilled in the art over the silica teaching of Richardson.

Regarding instant claims 12-14, the percentage of flow modifier would have been obvious to one skilled in the art over the Richardson teaching that "these additives are typically added in the range of 1 to 30 percent by weight" (Col. 9, lines 61-62).

Regarding instant claims 57-59, the limitations of the composition in feed pellet, premix for feed with the composition, and mash feed with the composition would have been obvious to one skilled in the art over the Richardson teaching that the encapsulated ingredient (choline chloride) is combined with a moist composition which is a ruminant feed (Col. 3, lines 54-55).

7. Claims 15-19, and 41-42, are rejected under 35 U.S.C. 103(a) as being unpatentable over Iijima et al. (US 4,948,589) in view of Brommelsiek et al. (US 5,766,668).

The teaching of Iijima is stated above.

Iijima does not expressly teach stearates as binders acting as moisture barriers in the core composition.

Brommelsiek teaches a choline feed stock precursor having greater than about 80-wt% of choline chloride, a lubricating agent, and an excipient (Abstract). Lubricants

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such as stearate salts are added to the spray drying system (Col. 7, lines 17-25). "The lubricant may be added during processing in concentrations which range from about 0 to 10 wt-% of the finished product ..." (Col. 7, lines 26-27). "The ratio of calcium stearate to choline chloride may range from about 0.01 to 1 to about 0.06 to 1" (Col. 7, lines 46-49).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a composition of choline chloride in the core, coated with hydrophobic materials such as carnauba wax and hydrogenated oils, as suggested by Iijima, and use lubricants such as stearate salts, as taught by Brommelsiek, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because inclusion of stearate salts as lubricants is "useful in producing a stable choline product ... this constituent assists in providing lubricity to the system during spray-drying and preventing deliquescence of the final composition" (Col. 4, lines 40-45). Since choline chloride is known in the art to be hygroscopic, using stearates to prevent the hygroscopic nature of the coated core of choline chloride would have been obvious to one skilled in the art. Even though Brommelsiek teaches spray drying liquid choline chloride, the end result is still a powdered choline chloride and lubricants are added to prevent deliquescence.

Regarding instant claims 18, the percentage of binder acting as a moisture barrier in the core would have been obvious to one skilled in the art given the teaching

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of Brommelsiek that 0-10% of lubricant can be used in the composition. One skilled in the art would vary the percentage during the process of routine experimentation.

8. Claims 20-21, 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iijima et al. (US 4,948,589) in view of Richardson (US 6,797,291), and further in view of Brommelsiek et al. (US 5,766,668).

The teaching of Iijima is stated above.

Iijima does not expressly teach silicates as flow modifiers or stearates as binders acting as moisture barriers in the core composition.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a composition of choline chloride in the core, coated with hydrophobic materials such as carnauba wax and hydrogenated oils, as suggested by Iijima, use silica as the flow agent, as taught by Richardson (see above), and use lubricants such as stearate salts, as taught by Brommelsiek (see above), and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Richardson teaches silica as a flow agent and Brommelsiek teaches lubricants such as stearates to reduce the hygroscopic nature of encapsulated choline chloride.

Regarding instant claims 20-21, 43-45, the limitations of percent choline chloride in the core, percent of flow modifier silica, percent of calcium stearate, percent of protective coating (outer and inner layers), and final particle size would have been obvious to one skilled given the teachings of Iijima, Richardson, and Brommelsiek. One

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skilled in the art would vary the levels of the components and coatings in order to optimize the stability of the choline chloride in the rumen. The percentages and particle sizes recited are obvious variants unless there is evidence of criticality or unexpected results.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1, 9-11, 16-17, 50, 52-54, and 57 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, and 7-10 of copending Application No. 11/228,818 ('818 hereinafter). Although the conflicting claims are not identical, they are not patentably distinct from each other.

The claimed invention is a composition of matter comprising particles with a core of choline chloride as a dry, crystalline powder and a coating of carnauba wax and a

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hydrophobic substance (selected from vegetable oils). Feed pellets, premix for feed, and mash feed containing the composition are also claimed.

Claims 1-4, and 7-10 of '818 are drawn to a composition of pellets with controlled release of physiologically active substances and comprising a core, which contains the active substance (including choline chloride), and a matrix of a carnauba wax, a first layer of coating of the core comprising a hydrophobic substance (selected from fats, hydrogenated oils etc.).

The difference between the coating of the core in the instant claims and the matrix and coated core of the claims of '818 would have been obvious to one skilled in the art at the time the invention was made. The components of the two compositions, including the active ingredient (choline chloride), the coating materials (carnauba wax) and hydrophobic substances (lipids, hydrogenated oils) are the same. One skilled in the art would be motivated to prevent choline chloride degradation in the acidic rumen environment and would use either a coating or coating and then dispersing the coated active within a matrix in order to achieve this goal. Since the instant application claims a composition of matter comprising a core and coating of choline chloride, it is obvious over the claims of '818, and they are not patentably distinct over each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.


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Conclusion

11. No claims are allowed.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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